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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,238	08/01/2003	Tilak M. Shah	4179-126	2458
23448	7590	12/08/2005	EXAMINER	
INTELLECTUAL PROPERTY / TECHNOLOGY LAW			FIDEI, DAVID	
PO BOX 14329			ART UNIT	
RESEARCH TRIANGLE PARK, NC 27709			PAPER NUMBER	
			3728	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/633,238	SHAH, TILAK M.	
	Examiner	Art Unit	
	David T. Fidei	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 18-20 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

Applicant's request for rejoinder of is acknowledged. The basis for rejoinder is allowance of pending article claim 1 and claim 20 being amended to depend from claim 1. Since claim 1 is not being allowed the request is denied. Were claim 1 ultimately found allowable (by amendment or judicial review) the Examiner would be agreeable to rejoinder of claims 18 and 19. However, claim 20 is a method of manufacture. In such claims structural limitations are of no patentable significance because the structure does not affect the method of making in any manipulative sense. The difference being the kit claims are positively relying on the structural limitations of the prior claims from which they depend for patentability and the burden of further searching would not be required. This not being the case in the method claims along with further searching of manufacturing methods being mandated, the Examiner would not be agreeable to such rejoinder. If such is not the case, the applicant is invited to describe the advantages gained over the method of claim 20 over the recitation of claim 7.

The requirement is still deemed proper and rejoinder denied.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1-7, 10-13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tobler (Patent no. 5,255,808). A tubular member 2 is disclosed in figure 2 having a closed distal end at 3 and an open proximal end at 5, with integral hinge elements 6 at opposing sides thereof for facilitating flattening of the tube, see figure 7.

As to claim 2 the tube has a conical distal portion at 17, note figure 2.

As to claims 3, 4, the open proximal end of the tube comprises coupling structure, threads, for mateable engagement with a cap, see col. 3, lines 35-37.

As to claim 5, the integral hinge elements are diametrically opposite one another.

As claim 6, figure 10 discloses a tube comprising concave depressions on an exterior surface of the tube, oppositely facing one another, between the respective integral hinge elements 106.

As to claim 7, process by which the tube is formed, i.e., by a molding technique selected from the group consisting of extrusion blow molding and rotational molding, is not seen as imparting a distinguishing characteristics over the prior.

A "product by process" claim is directed to the product per se, no matter how actually made, *In re Hirao*, 190 USPQ 15 at 17 (footnote 3). See also *In re Brown*, 173 USPQ 685; *In re Luck*, 177 USPQ 523; *In re Fessmann*, 180 USPQ 324; *In re Avery*, 186 USPQ 161; *In re Wertheim*, 191 USPQ 90; and *In re Marosi et al*, 218 USPQ 289, all of which make it clear that it is the patentability of the final product per se which must be determined in a "product by process" claim, and that an old or obvious product produced by a new method is not patentable as a product, whether claimed in "product by process" claims or not. During examination, the patentability of a product-by-process claim is determined by the novelty and non-obviousness of the claimed product itself without consideration of the process for making it which is recited in the claim. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985), M.P.E.P. § 2113.

As to claim 10, the tube of claim 1 has integral hinge elements 6 that extend along substantially the full length of the tube between its proximal and distal ends.

As to claim 11, the integral hinge elements 6 extend along only part of the length of the tube between its proximal and distal ends.

As to claims 12, wherein each of the integral hinge elements comprises a ridged structure, note figure 3 where the integral hinge element 6 is ridged outward.

As to claim 13, each of the elements 6 are constructed similar to element 13, see col. 3 line 66 to col. 4 line 2 and comprises a corrugated protrusion structure, note figure 5.

As to claims 15 and 16, polypropylene is disclosed in col. 6, line 16.

As to claim 17 the tube has a closed distal end 3 and an open proximal end 5, with an elongate main body portion 2 of generally cylindrical form, with integral hinge elements 6 at opposing sides of the main body portion, extending longitudinally along at least a portion of the length thereof, whereby manual compressive pressure exerted on respective exterior surfaces of the main body portion between the integral hinge elements will effect flattening of the tube at a region of compression of the main body portion, see figure 7.

4. Claims 1-5, 7, 10-14 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kasboske (Patent no. 6,170,712). A tubular member 14 is disclosed in figures 1-20 having a closed distal end at 17 and an open proximal end at 20, with integral hinge elements 30, 82, 100, 126 and 176 at opposing sides thereof for facilitating flattening of the tube, see col. 5, lines 55-65 where the volume of the structure is reduced.

As to claim 2, the tube has a conical distal portion in figures 4, 6 and 7.

As to claims 3, 4, the open proximal end of the tube comprises coupling structure, threads, for mateable engagement with a cap, see col. 5, lines 14-18.

As to claim 5, the integral hinge elements are diametrically opposite one another.

As to claim 7, process by which the tube is formed, i.e., by a molding technique selected from the group consisting of extrusion blow molding and rotational molding, is not seen as imparting a distinguishing characteristics over the prior.

A "product by process" claim is directed to the product per se, no matter how actually made, In re Hirao, 190 USPQ 15 at 17(footnote 3). See also In re Brown, 173 USPQ 685; In re Luck, 177 USPQ 523; In re Fessmann, 180 USPQ 324; In re Avery, 186 USPQ 161; In re Wertheim, 191 USPQ 90; and In re Marosi et al, 218 USPQ 289, all of which make it clear that it is the patentability of the final product per se which must be determined in a "product by

process" claim, and the an old or obvious product produced by a new method is not patentable as a product, whether claimed in "product by process" claims or not. During examination, the patentability of a product-by-process claim is determined by the novelty and non-obviousness of the claimed product itself without consideration of the process for making it which is recited in the claim. In re Thorpe, 227 USPQ 964 (Fed. Cir. 1985), M.P.E.P. § 2113.

As to claim 10, the tube of claim 1, each of the integral hinge elements extends along substantially the full length of the tube between its proximal and distal ends.

As to claim 11, the integral hinge elements extends along only part of the length of the tube between its proximal and distal ends in that the hinge elements do not extend to the opening 20.

As to claims 12, wherein each of the integral hinge elements comprises a ridged structure, note figures 3, 5, 8, 11, 14 and 18 where the integral hinge element is ridged outward.

As to claim 13, each of the elements can also be viewed as comprising a corrugated protrusion structure, note figures 3, 5, 8, 11, 14 and 18.

As to claim 14, each of the integral hinge elements in figures 3, 5, 8, 11, 14 and 18 comprises a protrusion of generally triangular cross-section.

As to claim 17 the tube has a closed distal end 17 and an open proximal end 20, with an elongate main body portion 14, 80, 98, 124, 160, 210 of generally cylindrical form, with integral hinge elements 30, 82, 100, 126 and 176 at opposing sides of the main body portion, extending longitudinally along at least a portion of the length thereof, whereby manual compressive pressure exerted on respective exterior surfaces of the main body portion between the integral hinge elements will effect flattening of the tube at a region of compression of the main body portion, see col. 5, lines 55-65 where the volume of the structure is reduced. Claim 17 has also been amended to recite the tube is of sufficient size and shape for placement in a centrifuge. Applicant's attention is directed to Kasboske col. 5; line 11 contemplates a container such as toothpaste. It a container of Kasboke sized to be a toothpaste container is envisioned as being of "sufficient size and shape for placement in a centrifuge" in as much as is claimed. Particularly where "travel" sized toothpaste containers come in same sizes.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 8, 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasboske (Patent no. 6,170,712). The difference between the claimed subject matter and Kasboske resides in the device having an inner diameter on the order of 1 inch and a length of from about 3 to about 8 inches. Claim 17 has been amended to recite the tube is of sufficient size and shape for placement in a centrifuge. Nothing is mentioned in Kasboske regarding the dimension of the container, but col. 5, lines 8-13 contemplates some uses for the container.

However, a change in size is generally recognized as being within the level of ordinary skill in the art. In *re Rose*, 105 USPQ 237 (CCPA 1955). Also, it has been held that where the only difference between the prior art device and the claimed device was a recitation of relative dimensions, the claimed device was not patentably distinct from the prior art device, *Gardner v. TED Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. Denied, 469 U.S. 830, 2325 USPQ 232 (1984), see M.P.E.P. 2144.04 (IV). It would have been an obvious matter of design choice to construct the container having an inner diameter on the order of 1 inch and a length of from about 3 to about 8 inches, since such a modification would have involved a mere

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change in the size of a component dependent upon how big or small one desires to package the contents of col. 5, lines 8-13.

8. Claims 8, 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobler (Patent no. 5,255,808). The difference between the claimed subject matter and Tobler resides in the device having an inner diameter on the order of 1 inch and a length of from about 3 to about 8 inches. Claim 17 has been amended to recite the tube is of sufficient size and shape for placement in a centrifuge. Nothing is mentioned in Tobler regarding the dimension of the container. However, a change in size is generally recognized as being within the level of ordinary skill in the art. In *re Rose*, 105 USPQ 237 (CCPA 1955). Also, it has been held that where the only difference between the prior art device and the claimed device was a recitation of relative dimensions, the claimed device was not patentably distinct from the prior art device, *Gardner v. TED Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. Denied, 469 U.S. 830, 2325 USPQ 232 (1984), see M.P.E.P. 2144.04 (IV).

It would have been an obvious matter of design choice to construct the container having an inner diameter on the order of 1 inch and a length of from about 3 to about 8 inches, since such a modification would have involved a mere change in the size of a component dependent upon how big or small one desires to package the contents of the bottle.

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over as applied above, and further in view of Amand (U.S. Patent no. 3,537,498). Both Kasboske (Patent no. 6,170,712) and Tobler (Patent no. 5,255,808) discloses the subject matter recited in new claim 21 except for a concave depression on an exterior surface facing one another. Amand teaches a concave depression on an exterior surface facing one another as shown in figure 1 by sections 2, 3. It would have been obvious to one of ordinary skill in the art to modify the containers of the prior art by constructing such a feature. The motivation for this modification is permit grasping thereof.

Response to Arguments

10. Applicant's arguments filed August 23, 2005 have been fully considered but they are not persuasive. On page 9, second to the last paragraph applicant acknowledges Tobler teaches the use of an outwardly yielding hinge elements. However, both inward and outward hinge elements are disclosed. In as much as Tobler discloses what applicant is claiming it is submitted this is sufficient to anticipate the present invention recited of the claim construction recite.

The Examiner realizes it is a fundamental tenet of patent law that the standard for anticipation is one of strict identity. To anticipate a claim for a patent, a single prior art reference must contain all of the elements recited in the claim.

"An anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice or device." *In re Donohue*, 766 F.2d 531, 266 USPQ 619, 621 (Fed. Cir. 1985).

"Exclusion of a claimed element from a prior art reference is enough to negate anticipation by that reference." *Atlas Powder Company v. E.I. du Pont De Nemours*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984).

However, the law of anticipation does not require that the reference teach what applicant has disclosed, but only that the claims "read on" something disclosed in the reference. See *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 281 USPQ 871 (Fed. Cir. 1983). The centrifuge tube is recited in claim 1 as having integral hinge elements wherein said integral hinge elements consist of outwardly yielding hinge elements. The claim construction is an "open" recitation where a prior art reference having the element recited can also include other elements and still satisfy the claim limitations. This scope is not limited by the later recitation "consist of". The holding is similar to *In re Crish*, 393 F.3d 1253, 73 USPQ2d 1364 (Fed. Cir. 2004). In determining the scope of applicant's claims directed to "a purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1 wherein said portion consists of the nucleotide sequence from ... to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity," the court stated that the use of "consists" in the body of the claims did not limit the open-ended "comprising" language in the claims (emphases added). *Id.* At 1257, 73 USPQ2d at 1367.

Furthermore, it is not seen where the hinge elements 6 fail to satisfy the standard of In re Bond. Particularly, where the elements are not arranged as recited in the claim. As noted above there are opposing hinge elements designated by folding lines 6. These integral hinge elements consists of outwardly extending elements as shown in figure 3. While it is acknowledged Tobler has folding lines 7 and 8, it is not clear what is meant by inwardly folding. If inwardly folding is perceived by applicant to be the folding of top portion 4 and lower portion 17, then it is not seen where this is pertinent to the subject matter of claim 1. The open construction of the hinge elements referenced in claim 1 can be viewed as any hinge element at opposing sides. Elements 6 of Tobler full meet the claim limitations between points 9 & 10 as nothing is recited in the claim excluding the arrangement of the other element. Accordingly, the rejection is maintained.

As to claim 17 it is acknowledged Tobler does not appear to provide a tube of sufficient size for placement in a centrifuge. However, that is not to say such a modification would have involved an inventive step. As noted above a change in size is not considered to be anything more than a routine variation.

With regard to Kasboske (Patent no. 6,170,712) the same analogy is applied as with Tobler. While there are inward and outward elements, outwardly extending hinge elements, e.g., 31, 32 are provided on opposite sides. In this regard it is not seen where the patent to Kasboske is ambiguous. A fold line is defined that extend substantially between the top and bottom of the container. These fold lines form a integral hinge elements in as much as is claimed. Also various fold structures are disclosed that include an outwardly yielding hinge element. Beyond understanding Kasboske disclosing this subject matter, it not seen where any ambiguity to figure 16 is relevant to the issues at hand.

Applicant's argument that Kasboske teaches away from centrifugation is not germane to the claimed subject matter. Dictionary.com defines "centrifugation" as the process of separating substances by the use of a centrifuge. Nowhere in any of the pending claims is any such process set forth. Accordingly, applicant's remarks in this regard are moot.

Claim Rejections Under 35 USC § 103

As to Kasboske and Tobler failing to teach every limitation of claim 1, it appears applicant is arguing obviousness based upon a lacking of novelty. The failure to address specific distinctions is a concession by the applicant that, if the ground of rejection were sustained as to any one of the rejected claims, it will be equally applicable to all of them. This is consistent with the practice of the Court of Appeals for the Federal Circuit indicated in such cases as *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991); *In re Nielson*, 816 F.2d 1567, 2 USPQ2d 1525 (Fed. Cir. 1987); *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986); and *In re Sernaker*, 702 F.2d 989, 217 USPQ 1 (Fed. Cir. 1983).

With regard to new claim 21, concave depressions on the exterior surfaces of containers are well known as demonstrated by the prior art further cited. To merely modify the containers of Kasboske and Tobler by constructing a concave depression would have been *prima facie* in view of Amand (U.S. Patent no. 3,537,498). Accordingly, it is submitted claim 21 defines nothing novel over the prior art as would have been recognized by one skilled in the art.

Conclusion


11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the Examiner concerning the merits of the claims should be directed to David T. Fidei whose telephone number is (571) 272-4553. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David T. Fidei
Primary Examiner
Art Unit 3728

dtf
August 8, 2005